

A COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

Between
[Insert name and address]
(Cooperator)

and

Walter Reed Army Institute of Research
503 Robert Grant Avenue
Silver Spring, MD 20910-7500
(Laboratory)

Article 1. Background

1.00 This Agreement is entered into under the authority of the Federal Technology Transfer Act of 1986, 15 U.S.C. 3710a, et seq., between the Cooperator and the Laboratory, the parties to this Agreement.

1.01 Laboratory, on behalf of the U.S. Government, and Cooperator desire to cooperate in research and development on **[insert title]** according to the attached Scope of Work (SOW) described in Appendix A. NOW, THEREFORE, the parties agree as follows:

Article 2. Definitions

2.00 The following terms are defined for this Agreement as follows:

2.01 "Agreement" means this cooperative research and development agreement.

2.02 "Invention" and "Made" have the meanings set forth in Title 15 U.S.C. Section 3703(9) and (10).

2.03 "Proprietary Information" means information marked with a proprietary legend which embodies trade secrets developed at private expense or which is confidential business or financial information, provided that such information:

(i) is not generally known, or which becomes generally known or available during the period of this Agreement from other sources without obligations concerning their confidentiality;

(ii) has not been made available by the owners to others without obligation concerning its confidentiality; and

(iii) is not already available to the receiving party without obligation concerning its confidentiality.

(iv) is not independently developed by or on behalf of the receiving party, without reliance on the information received hereunder.

2.04 "Subject Data" means all recorded information first produced in the performance of this Agreement.

2.05 "Subject Invention" means any Invention Made as a consequence of, or in relation to, the performance of work under this Agreement.

Article 3. Research Scope and Administration

3.00 Scope of Work. Research performed under this Agreement shall be performed in accordance with the SOW incorporated as a part of this Agreement at Appendix A. It is agreed that any descriptions, statements, or specifications in the SOW shall be interpreted as goals and objectives of the services to be provided under this Agreement and not requirements or warranties. Laboratory and Cooperator will endeavor to achieve the goals and objectives of such services; however, each party acknowledges that such goals and objectives, or any anticipated schedule of performance, may not be achieved.

3.01 Review of Work. Periodic conferences shall be held between the parties for the purpose of reviewing the progress of work. It is understood that the nature of this research is such that completion within the period of performance specified, or within the limits of financial support allocated, cannot be guaranteed. Accordingly, all research will be performed in good faith.

3.02 Principal Investigator. Any work required by the Laboratory under the SOW will be performed under the supervision of **[insert (name, address, phone, FAX and Email)]**, who, as co-principal investigator has responsibility for the scientific and technical conduct of this project on behalf of the Laboratory. Any work required by the Cooperator under the SOW will be performed under the supervision of **[insert (name, address, phone, FAX and Email)]**, who, as co-principal investigator has responsibility for the scientific and technical conduct of this project on behalf of the Cooperator.

3.03 Scope Change. If at any time the co-principal investigators determine that the research data dictates a substantial change in the direction of the work, the parties shall make a good faith effort to agree on any necessary change to the SOW and make the change by written notice to the address listed in section 12.07 Notices.

3.04 Final Report. The parties shall prepare a final report of the results of this project within

six months after completing the SOW.

Article 4. Ownership and Use of Physical Property

4.1 Ownership of Materials or Equipment. All materials or equipment developed or acquired under this Agreement by the parties shall be the property of the party which developed or acquired the property, except that government equipment provided by Laboratory (1) which through mixed funding or mixed development must be integrated into a larger system, or (2) which through normal use at the termination of the Agreement has a salvage value that is less than the return shipping costs, shall become the property of Cooperator.

4.2 Use of Provided Materials. Both parties agree that any materials relating to them which were provided by one party to the other party will be used for research purposes only. The materials shall not be sold, offered for sale, used for commercial purposes, or be furnished to any other party without advance written approval from the Provider's official signing this Agreement or from another official to whom the authority has been delegated, and any use or furnishing of material shall be subject to the restrictions and obligations imposed by this Agreement.

Article 5. Financial Obligation [where applicable- see below for alternate]

5.00 Advance Payment. The performance of research by Laboratory under this Agreement is conditioned on the advance payment by Cooperator of Laboratory's agreed upon costs for the performance of such research.

5.01 Deposit Account. Cooperator shall pay a total of (upto)_____ to Laboratory for the performance of the research specified by Article 3.00. A schedule of payments is attached as Appendix B (use if there are several payments over time). Such funds shall be deposited in [Department of the Army, Special Collaborative Agreement Account No. _____] upon execution of this agreement. The check(s) should be made payable to "U.S. Treasury/WRAIR) and send to:

Office of Research and Technology Applications
ATTN: Claudia Golenda
Walter Reed Army Institute of Research
503 Robert Grant Avenue
Silver Spring, Maryland 20910-7500

Laboratory shall not be obligated to perform any of the research specified herein or to take any other action required by this Agreement if the agreed to funds are not deposited as required by this Article.

5.02 Insufficient and Excess Funds. Laboratory shall not be required to continue its research and development activities under this Agreement if the funds provided by Cooperator are insufficient to cover Laboratory's agreed upon costs for such continued activities. Funds not expended by Laboratory shall be returned to Cooperator upon Laboratory's submission of a final fiscal report to Cooperator.

5.03 Accounting Records. Laboratory shall maintain separate and distinct current accounts, records, and other evidence supporting all its expenditures under this Agreement. Laboratory shall provide Cooperator a semi-annual report accounting for the use of Cooperator's funds and a final fiscal report within 4 months after completing the SOW or ending its research activities under this Agreement. The accounts and records of Laboratory shall be available for reasonable inspection and copying by Cooperator and its authorized representative.

IF NOT APPLICATIBLE (UNFUNDED), INCLUDE THE FOLLOWING:

5.00 Funding. The parties shall each be individually responsible for funding its own respective researchers throughout this Agreement, including laboratory facilities, salaries, overhead and indirect costs, etc. Each party may determine at its own discretion, the amount of resources, personnel, materials or funds it will devote to the work under this Agreement.

5.01 Expenses. The parties shall each be individually responsible for expenses incurred by their respective researchers. Neither party shall be liable or obligated to any third party contractual agreement undertaken by the other party.

Article 6. Patent Rights

6.00 Reporting. The parties shall promptly report to each other all Subject Inventions reported to either party by its employees. All Subject Inventions Made during the performance of this Agreement shall be listed in the Final Report required by this Agreement.

6.01 Cooperator Employee Inventions. Laboratory waives any ownership rights the U.S. Government may have in Subject Inventions Made by Cooperator employees and agrees that Cooperator shall have the option to retain title in Subject Inventions Made by Cooperator employees. Cooperator shall notify Laboratory promptly upon making this election and agrees to timely file patent applications on Cooperator's Subject Invention at its own expense. Cooperator agrees to grant to the U.S. Government on Cooperator's Subject Inventions a nonexclusive, nontransferable, irrevocable, paid-up license in the patents covering a Subject Invention, to practice or have practiced, throughout the world by, or on behalf of the U.S. Government. The nonexclusive license shall be evidenced by a confirmatory license agreement prepared by Cooperator in a form satisfactory to Laboratory.

6.02 Laboratory Employee Inventions. Laboratory shall have the initial option to retain title

to, and file patent application on, each Subject Invention Made by its employees. The Laboratory agrees to grant an exclusive license to any invention arising under this Agreement to which it has ownership to the Cooperator in accordance with Title 15 U.S. Code Section 3710a, on terms negotiated in good faith. Any invention arising under this Agreement is subject to the retention by the U.S. Government of nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced, the invention throughout the world by or on behalf of the U.S. Government.

6.03 Joint Inventions. Any Subject Invention patentable under U.S. patent law which is Made jointly by Laboratory employees and Cooperator employees under the Scope of Work of this Agreement shall be jointly owned by the parties. The parties shall discuss together a filing strategy and filing expenses related to the filing of the patent covering the Subject Invention. If a party decides not to retain its ownership rights to a jointly owned Subject Invention, it shall offer to assign such rights to the other party, pursuant to Paragraph 6.04, below.

6.04 Government Contractor Inventions. In accordance with 37 Code of Federal Regulations 401.14, if one of Laboratory's Contractors conceives an invention while performing services at Laboratory to fulfill Laboratory's obligations under this Agreement, Laboratory may require the Contractor to negotiate a separate agreement with Cooperator regarding allocation of rights to any Subject Invention the Contractor makes, solely or jointly, under this Agreement. The separate agreement (i.e., between the Cooperator and the Contractor) shall be negotiated prior to the Contractor undertaking work under this Agreement or, with the Laboratory's permission, upon the identification of a Subject Invention. In the absence of such a separate agreement, the Contractor agrees to grant the Cooperator an option for a license in Contractor's inventions of the same scope and terms set forth in this Agreement for inventions made by Laboratory employees.

6.05 Filing of Patent Applications. The party having the right to retain title to, and file patent applications on, a specific Subject Invention may elect not to file patent applications, provided it so advises the other party within 90 days from the date it reports the Subject Invention to the other party. Thereafter, the other party may elect to file patent applications on the Subject Invention and the party initially reporting the Subject Invention agrees to assign its ownership interest in the Subject Invention to the other party subject to the retention by the party assigning ownership of a nonexclusive, irrevocable, paid-up license to practice, or have practiced, the Subject Invention throughout the world.

6.06 Patent Expenses. The expenses attendant to the filing of patent applications shall be borne by the party filing the patent application. Each party shall provide the other party with copies of the patent applications it files on any Subject Invention along with the power to inspect and make copies of all documents retained in the official patent application files by the applicable patent office. The parties agree to reasonably cooperate with each other in the preparation and filing of patent applications resulting from this Agreement.

Article 7. Exclusive License

7.00 Grant. The Laboratory agrees to grant to the Cooperator an exclusive license in each U.S. patent application, and patents issued thereon, covering a Subject Invention, which is filed by the Laboratory subject to the reservation of a nonexclusive, nontransferable, irrevocable, paid-up license to practice and have practiced the Subject Invention on behalf of the United States.

7.01 Exclusive License Terms. The Cooperator shall elect or decline to exercise its right to acquire an exclusive license to any Subject Invention within six months of being informed by the Laboratory of the Subject Invention. The specific royalty rate and other terms of license shall be negotiated promptly in good faith and in conformance with the laws of the United States.

Article 8. Background Patent(s)

8.00 Laboratory Background Patent(s): Laboratory has filed patent application(s), or is the assignee of issued patent(s), listed below which contain(s) claims that are related to research contemplated under this Agreement. No license(s) to this/these patent applications or issue patents is/are granted under this Agreement, and this/these application(s) and any continuations to it/them are specifically excluded from the definitions of “Subject Invention” contained in this Agreement:

8.01 Cooperator Background Patent(s): Cooperator has filed patent application(s), or is the assignee of issued patent(s), listed below which contain(s) claims that are related to research contemplated under this Agreement. No license(s) to this/these patent applications or issue patents is/are granted under this Agreement, and this/these application(s) and any continuations to it/them are specifically excluded from the definitions of “Subject Invention” contained in this Agreement:

Article 9. Subject Data and Proprietary Information

9.00 Subject Data Ownership. Subject Data shall be jointly owned by the parties. Either party shall have the right to review all Subject Data that has not been delivered to the other party, except to the extent that such Subject Data are subject to a claim of confidentiality or privilege by a third party.

9.01 Proprietary Information/Confidential Information. Each party shall place a proprietary notice on all information it delivers to the other party under this Agreement which it asserts is proprietary. The parties agree that any Proprietary Information or Confidential Information furnished by one party to the other party under this Agreement, or in contemplation of this Agreement, shall be used, reproduced and disclosed by the receiving party only for the purpose of carrying out this Agreement, and shall not be released by the receiving party to third parties

unless consent to such release is obtained from the providing party.

9.02 Army limited-access database. Notwithstanding anything to the contrary in this Article, the existence of established CRADAs specifying areas of research and their total dollar amounts may be documented on limited access, password-protected websites of the U.S. Army Medical Research and Materiel Command (the parent organization of Laboratory), to provide the Command's leadership with a complete picture of military research efforts.

9.03 Laboratory Contractors. Cooperator acknowledges and agrees to allow Laboratory's disclosure of Cooperator's proprietary information to Laboratory's Contractors for the purposes of carrying out this Agreement. Laboratory agrees that it has or will ensure that its Contractors are under written obligation not to disclose Cooperator's proprietary information, except as required by law or court order, before Contractor employees have access to Cooperator's proprietary information under this Agreement.

9.04 Release Restrictions. Laboratory shall have the right to use all Subject Data for any Governmental purpose, but shall not release Subject Data publicly except: (i) Laboratory in reporting on the results of research may publish Subject Data in technical articles and other documents to the extent it determines to be appropriate; and (ii) Laboratory may release Subject Data where release is required by law or court order. The parties agree to confer prior to the publication of Subject Data to assure that no Proprietary Information is released and that patent rights are not jeopardized. Prior to submitting a manuscript for review which contains the results of the research under this Agreement, or prior to publication if no such review is made, each party shall be offered an ample opportunity to review any proposed manuscript and to file patent applications in a timely manner.

9.05 FDA Documents. If this Agreement involves a product regulated by the U.S. Food and Drug Administration (FDA), then the Cooperator or the U.S. Army Medical Research and Materiel Command, as appropriate, may file any required documentation with the FDA. In addition, the parties authorize and consent to allow each other or their contractors or agents access to, or to cross-reference, any documents filed with the FDA related to the product.

Alternate 9.04 EPA Registration. The parties agree that either party may apply for any Environmental Protection Agency (EPA) registration required for any resultant product of the Agreement unless one party otherwise specifically grants permission to the other party to do so. All safety data used for such application for EPA registration shall be provided to the non-applying party within thirty (30) days of submission to the EPA.

Article 10. Termination

10.00 Termination by Mutual Consent. Cooperator and Laboratory may elect to terminate this Agreement, or portions thereof, at any time by mutual consent.

10.01 Termination by Unilateral Action. Either party may unilaterally terminate this entire Agreement at any time by giving the other party written notice, not less than 30 days prior to the desired termination date.

10.02 Termination Procedures. In the event of termination, the parties shall specify the disposition of all property, patents and other results of work accomplished or in progress, arising from or performed under this Agreement by written notice. Upon receipt of a written termination notice, the parties shall not make any new commitments and shall, to the extent feasible, cancel all outstanding commitments that relate to this Agreement. Notwithstanding any other provision of this Agreement, any exclusive license entered into by the parties relating to this Agreement shall be simultaneously terminated unless the parties agree to retain such exclusive license.

10.03. Termination Costs(If funded): Within 90 days following termination of this Agreement, the Laboratory shall submit a statement of all costs incurred prior to the date of termination and for all termination costs. Any unspent funds provided to the Laboratory by Cooperator shall be used to fund termination costs. In the event funds are insufficient to cover all of the termination costs, the Cooperator agrees to promptly meet with Laboratory to reach a settlement agreement regarding the payment of the remaining termination costs.

Article 11. Disputes

11.00 Settlement. Any dispute arising under this Agreement which is not disposed of by agreement of the principal investigators shall be submitted jointly to the signatories of this Agreement. A joint decision of the signatories or their designees shall be the disposition of such dispute. However, nothing in this section shall prevent any party from pursuing any and all administrative and/or judicial remedies which may be allowable.

Article 12. Liability

12.00 Property. Neither party shall be responsible for damages to any property provided to, or acquired by, the other party pursuant to this Agreement.

12.01 Cooperator's Employees. Cooperator agrees to indemnify and hold harmless the U.S. Government for liability of any kind involving an employee of Cooperator arising in connection with this Agreement, and for all liabilities arising out of the use by Cooperator of Laboratory's research and technical developments, or out of any use, sale or other disposition by Cooperator of products made based on Laboratory's technical developments, except to the extent the liability is due to the negligence of Laboratory under the provisions of the Federal Torts Claims Act. This provision shall survive termination or expiration of this Agreement.

12.02 No Warranty. The parties make no express or implied warranty as to any matter

whatsoever, including the conditions of the research or any Invention or product, whether tangible or intangible, Made, or developed under this agreement, or the ownership, merchantability, or fitness for a particular purpose of the research or any Invention or product.

Article 13. Miscellaneous

13.00 Governing Law. This Agreement shall be governed by the laws of the United States Government.

13.01 Export Control and Biological Select Agents and Toxins. The obligations of the parties to transfer technology to one or more other parties, provide technical information and reports to one or more other parties, and otherwise perform under this Agreement are contingent upon compliance with applicable United States export control laws and regulations. The transfer of certain technical data and commodities may require a license from a cognizant agency of the United States Government or written assurances by the Parties that the Parties shall not export technical data, computer software, or certain commodities to specified foreign countries without prior approval of an appropriate agency of the United States Government. The Parties do not, alone or collectively, represent that a license shall not be required, nor that, if required, it shall be issued. In addition, where applicable, the parties agree to fully comply with all laws, regulations, and guidelines governing biological select agents and toxins.

13.01 Independent Contractors. The relationship of the parties to this Agreement is that of independent contractors and not as agents of each other or as joint venturers or partners.

13.02 Use of Name or Endorsements. (a) The parties shall not use the name of the other party on any product or service which is directly or indirectly related to either this Agreement or any patent license or assignment agreement which implements this Agreement without the prior approval of the other party. (b) By entering into this Agreement, Laboratory does not directly or indirectly endorse any product or service provided, or to be provided, by Cooperator, its successors, assignees, or licensees. Cooperator shall not in any way imply that this Agreement is an endorsement of any such product or service. Press releases or other public releases of information shall be coordinated between the parties prior to release, except that the Laboratory may release the name of the Cooperator and the title of the research without prior approval from the Cooperator.

13.03 Survival of Specified Provisions. The rights specified in provisions of this Agreement covering Patent Rights, Subject Data and Proprietary Information, and Liability shall survive the termination or expiration of this Agreement.

13.04 FDA Regulated Products. If this Agreement involves a product regulated by the FDA, then the parties consent and authorize each other and their designated agents or contractors to have access to, and to cross-reference, any documents filed with the FDA relating to the product.

13.05 Notices. All notices pertaining to or required by this Agreement shall be in writing and shall be signed by an authorized representative addressed as follows:

If to Cooperator: **[insert contact information]**

If to Laboratory: Director
Walter Reed Army Institute of Research
ATTN: Office of Research and Technology Applications
503 Robert Grant Avenue
Silver Spring, MD 20910-7500

Any party may change such address by notice given to the other in the manner set forth above.

Article 14. Duration of Agreement and Effective Date

14.01 Effective Date. This Agreement shall enter into force as of the date it is signed by the last authorized representative of the parties.

14.02 Expiration Date. This Agreement will automatically expire **[insert # of years, as appropriate—no more than 3]** years from effective date unless it is revised by written notice and mutual agreement.

IN WITNESS WHEREOF, the Parties have caused this agreement to be executed by their duly authorized representatives as follows:

For the **Cooperator**:

DATE _____

(Please fill in name and title)

For the **U.S. Government**:

Date _____

Charles E. McQueen
COL, U.S. Army
Director, Walter Reed Army
Institute of Research

APPENDIX A SCOPE OF WORK

Title: [Provide a title for the Agreement. Example: “Research on the Chemotherapy of the Common Cold”]

Background: [Give a brief, clear, and concise statement (about ½ to ¾ page) of the background of the research and development project/program, and the reason(s) for this CRADA. Stress the scientific rationale for this CRADA and the technologies that are being transferred. Indicate the unique resources, technologies, and capabilities of the CRADA parties that will be brought to the collaboration. Specify if any of the parties’ resources or technologies are proprietary.]

Scope:

Laboratory agrees to:

1. [Make specific statements, in bullet format, as to what the laboratory will be committed to do under this Agreement.]

2.

3.

etc.

Collaborator agrees to:

1. [Make specific statements, in bullet format, as to what the collaborator will be committed to do under this Agreement.]

2.

3.

etc.

[where applicable] From time to time, Laboratory personnel may work in Collaborator’s laboratories and Collaborator’s personnel may work in Laboratory’s laboratory as necessary to accomplish the goals of this collaboration.

[Continue on additional page(s), if necessary.]